

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	Sevigny et al.
Serial No.	10/506,723
Filing Date	July 25, 2005
Art Unit	1791
Confirmation No.	5174
Examiner	Khare
Title	<b>APPARATUS FOR THE MANUFACTURE OF A DISPOSABLE ELECTROPHORESIS CASSETTE AND METHOD THEREOF</b>
Attorney Docket No.	073986.33

**DECLARATION OF PIERRE SEVIGNY UNDER 37 C.F.R. §1.131**

I, Pierre Sevigny, declare as follows:

I am a co-inventor of the subject matter disclosed and claimed in the referenced patent application.

I am making this Declaration to establish invention of the subject matter claimed in my application prior to March 8, 2001. I understand that March 8, 2001 is the prior art date of Roy WO 01/16589, which the Examiner has applied to reject my application.

To support my Declaration, I have attached documents, containing drawings, a photograph, and other informational material that fully illustrate and describe my invention in a manner sufficient such that a person of ordinary skill in the art could practice my invention without undue experimentation. All dates of the attached documents are prior to March 8, 2001.

The attached documents establish conception and reduction to practice of the subject matter I have disclosed and claimed prior to March 8, 2001. Specifically, the attached documents describe the manufacture of electrophoresis cassettes using a thermoforming process. For example, I have attached the drawing "Pre-Casted Gel Cassette Concept 2," which shows a disposable electrophoresis cassette that includes a clear thermoplastic upper plate and a clear plastic lower plate with integrated wells. I have also attached the information "Precast Gels, Native Elpho" which addresses "Cost Analysis (Preliminary Data)" about production of disposable electrophoresis cassettes using thermoforming. It also addresses casting and polymerization required to mold the disposable electrophoresis cassettes.

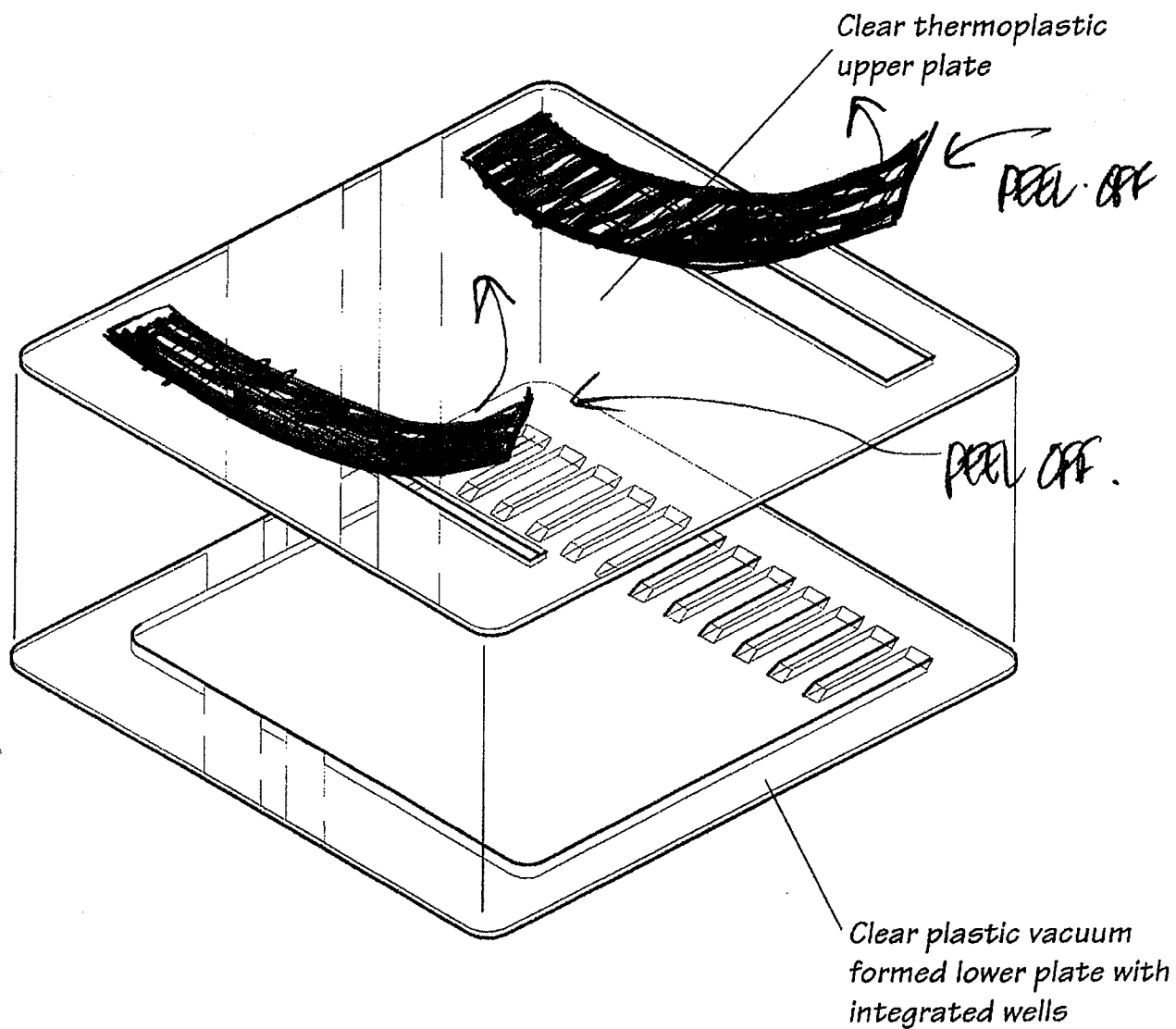
I diligently continued to refine various details of the invention from prior to March 8, 2001 until the March 7, 2002 filing of parent application (U.S. Patent Application Serial No. 10/091,549), from

which the above-referenced application claims priority. This diligence included, among other things, refining techniques, processes and logistics for cost-effectively manufacturing the invention, conferring with attorneys to evaluate the merits of the invention, and participating in preparing a patent application fully disclosing and claiming the invention. For example, as shown in the attached photograph, which was taken on January 1, 2000, we encountered surface flatness problems which translated into crooked migration and unusable data. This can be seen by the bead distribution in depressed areas of the cassette, due to bad forming. The surface flatness problems resulted in crooked migration and unusable data. The diligent research work required to correct this problem lasted until 2003.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the subject application or any patent issued thereon.

January 15, 2010  
Date  
755830

  
\_\_\_\_\_  
Pierre Seigny

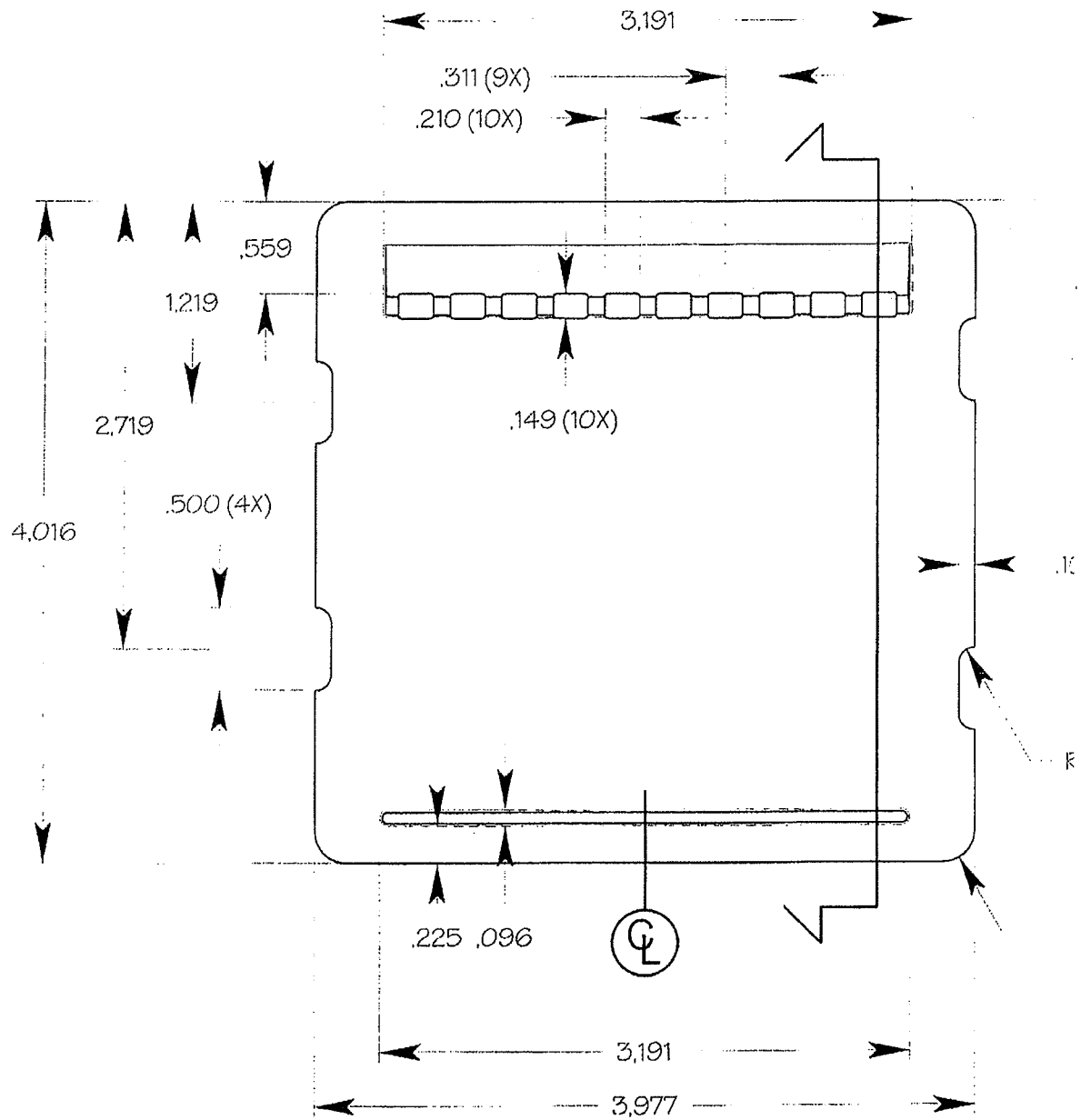


## Pre-casted gel cassette concept 2

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**MIRADOR  
DESIGN  
INDUSTRIEL**  
Mtl, Canada





# MIRADOR DESIGN INDUSTRIEL

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Design: Dominique Roy

Dessin/Drawing Dominique Roy

Date:

Echelle/Scale: 1:1

Client:

**FMC BIOPRODUCTS**

191 Thomaston street

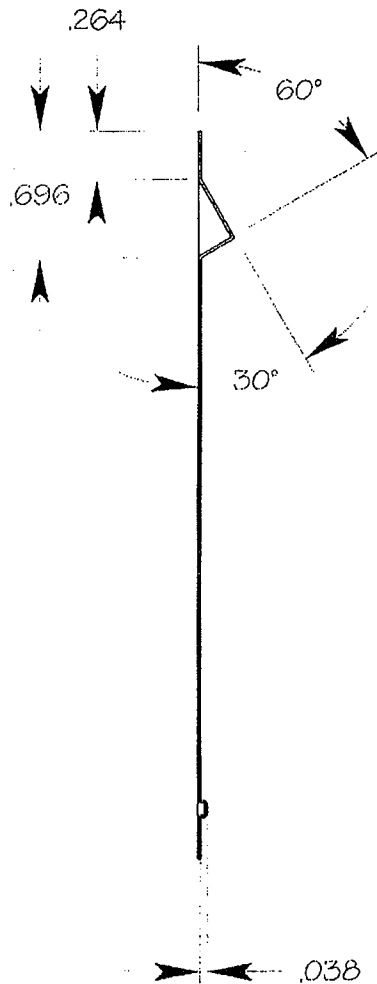
Rockland Maine

United States

Revision: no.: 3

approved/approuvé

**COVER**  
**SoftGel Project**

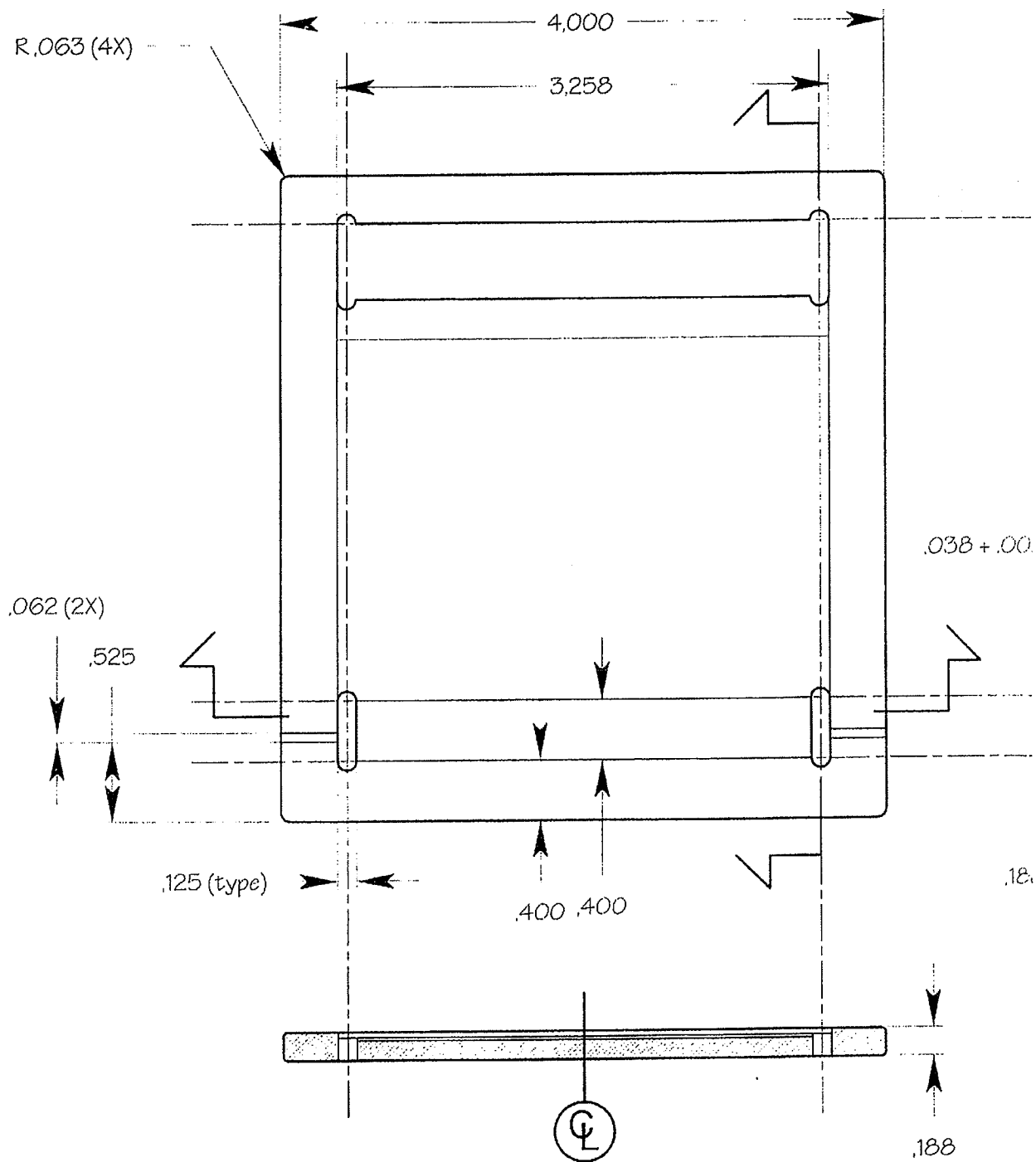


2.969

0.04 (4X)

0.04 (8X)

3.197 (4X)





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Dessin/Drawing Dominique Roy

Date:

Echelle/Scale: 1:1

Client:

**FMC BIOPRODUCTS**

191 Thomaston street

Rockland Maine

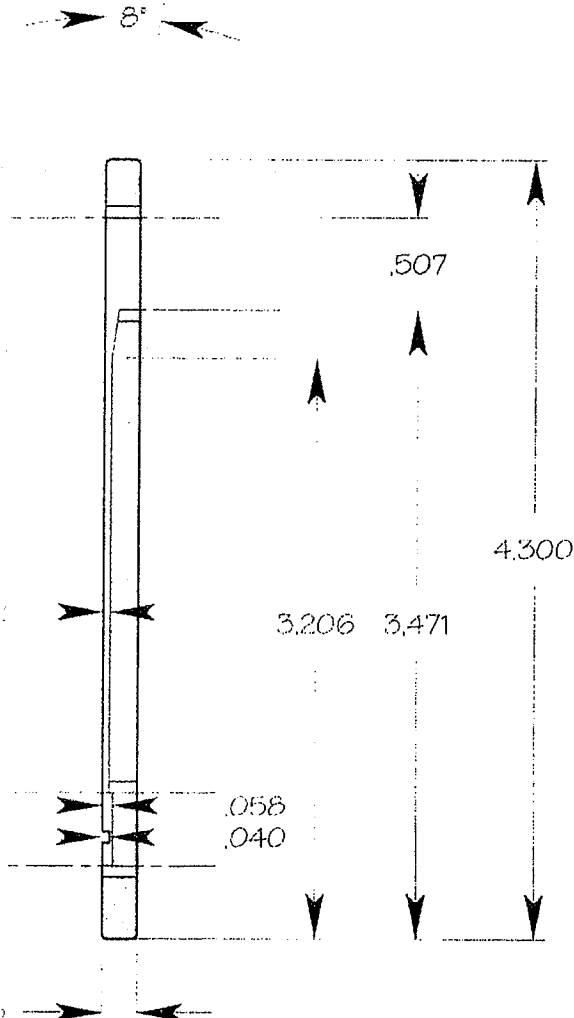
United States

Revision:

N/A

approved/approuvé

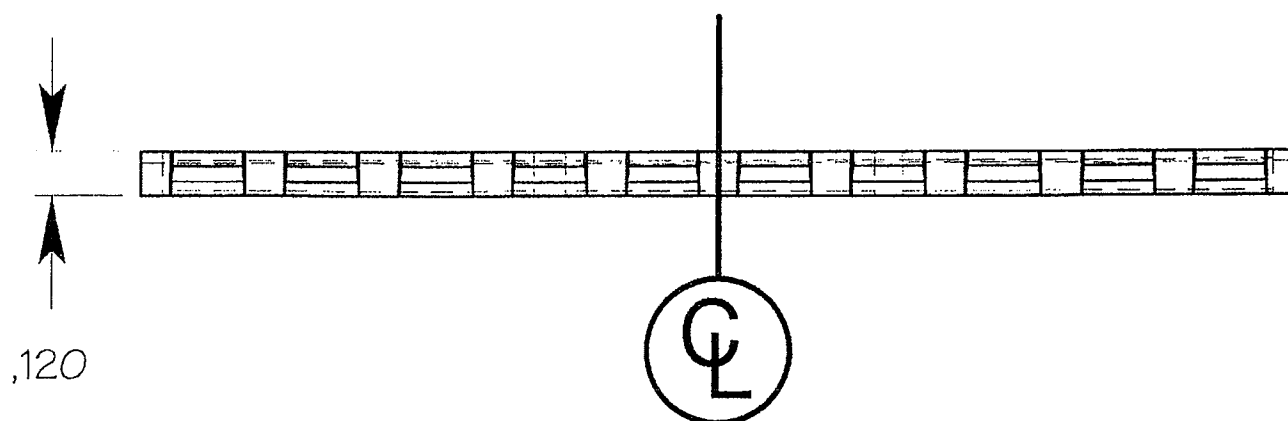
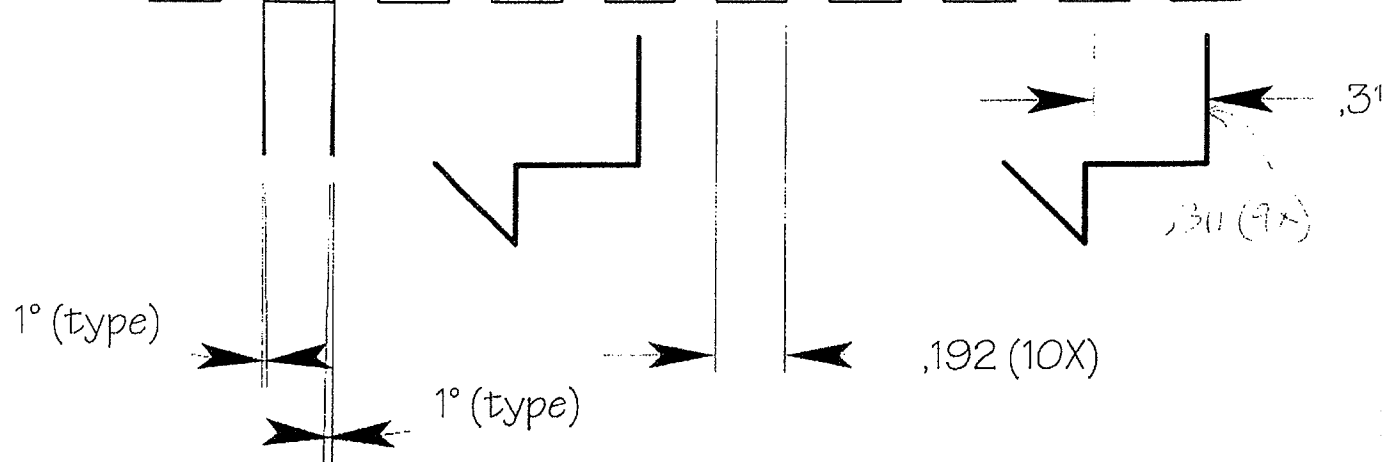
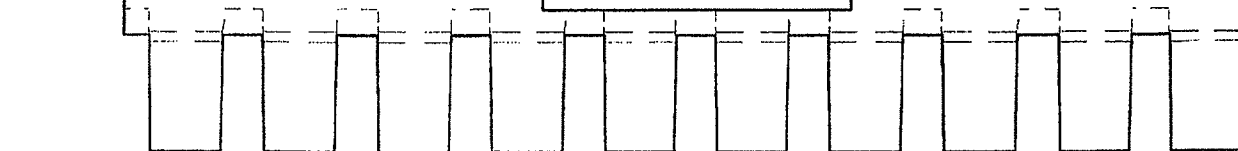
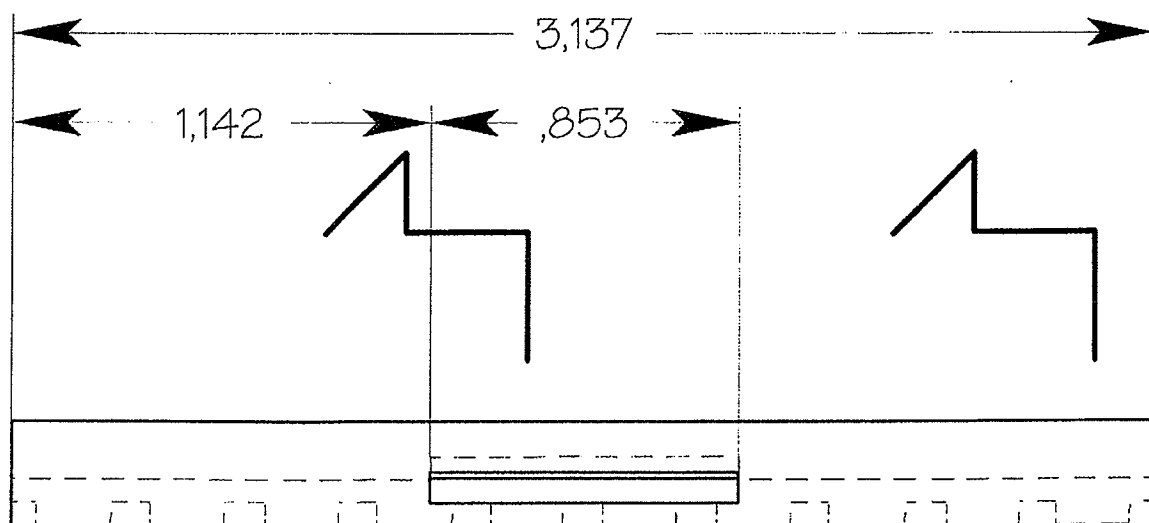
**FILLING FIXTURE**  
**SoftGel Project**



Matériau: aluminium

Tolérance: +/- .005

Note: Toutes les arêtes vives devront  
être adoucies







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Design: Dominique Roy

Dessin/Drawing: Dominique Roy

Date:

Echelle/Scale: 2:1

Client: **FMC BIOPRODUCTS**

191 Thomaston street

Rockland Maine

United States

Revision: N/A

approved/approuvé

Matériau: aluminium  
Tolérances: +/- .005 "

**COMB**  
**SoftGel Project**

## PRECAST GELS, native elpho

GenID - Gene Investigation and Design

Meeting the Needs: Pre-cast gel production

- By combining strength:
  - » **FMC** (Chemistry access, production facilities and sales structure)
  - » **GenID** (*SoftGel*<sup>™</sup> concept and adequate gel recipe on plastic)

[REDACTED]

## PRECAST GELS, native elpho

GenID - Gene investigation and Design

- **Cost Analysis** (preliminary data)
  - » Production costs:
    - Gel cassette (*SoftGel*<sup>™</sup> concept)  
[REDACTED]
    - Polymerization
      - neg. [REDACTED] use less than mg per gel)
    - Gel matrix and recipe
      - According to FMC production costs

[REDACTED]

# PRECAST GELS, native elpho

GenID - Gene investigation and Design

- Cost Analysis (preliminary data)
  - » Investments for production:
    - Thermoforming and Cassette assembly  
[REDACTED]
    - Casting and Polymerization
      - around [REDACTED]

[REDACTED]

# PRECAST GELS, native elpho

GenID - Gene investigation and Design

## Pros, Slide #1


- Low production cost [REDACTED] US\$, while we estimate a PC of [REDACTED] for competitors like [REDACTED]
- No need to pre-treat and/or coat the plastic film before casting;
- Fast set up time and low cost tooling required to set a production line. [REDACTED] for the SoftGel™ concept, compared to [REDACTED] for injection molding like [REDACTED];
- Environmentally freindly concern: Gel cassette with less or no waste for packaging (using 8 grams Vs 60 grams for the competitors like the [REDACTED] gel) and less waste for packaging;

[REDACTED]

# PRECAST GELS, native elpho

GenID - Gene Investigation and Design


## Pros, Slide #2

- The very quick polymerization of the gel improves its reliability and batch to batch low variations;
  - Design to accommodate all types of gels. Agarose (the cassette is thermo-resistant enough to endure such production) and PAGE under every denaturant or not recipe and concentration (the polymerization is not restricted to the type of matrix or common salts and denaturation compounds);
  - Design to fit all actual marketed electrophoresis boxes;
  - Integrated comb (no combs are required for the gel casting);
  - Easy loading with our leak free wells concept;
- 

# PRECAST GELS, native elpho

GenID - Gene Investigation and Design

## Pros, Slide #3

- Horizontal or classical Vertical loading of samples (improved design to ease loading and handling for the user, as well as the design could create more differentiability to help the producer get a solid patent for the complete concept);
  - The *SoftGel*™ concept allows to run these gels quicker at higher voltage, with no risks of braking the glass of the gel cassette;
  - Easy pop-out gel for transfer and/or staining (due to flexibility of the cassette, non-sticking surface and tear-off concept);
- 

# PRECAST GELS, native elpho

GenID - Gene investigation and Design

## Cons and concept production risks, Slide #1

- The structural concept complicates the gel casting (the cassette tends to inflate when the still liquid gel is poured into it);
- The cassette must stand vertically during casting and polymerization;
- The cassette frame is thinner than the actual common cassettes, which will require a special frame adapter for our gels fit the actual gel assembly;
- More restricted number of samples per gel;

# PRECAST GELS, native elpho

GenID - Gene investigation and Design

## Cons and concept production risks, Slide #2


- Aging of the gel in the cassette is still unknown. Its shelf life has to be closely investigated;
- Long term variability between gels due to the aging of the production UV lamps;
- Our *SoftGel*<sup>™</sup> concept requiring less packaging, the transportation consequences on the cassette have to be closely investigated.

# PRECAST GELS, native elpho

GenID - Gene investigation and Design

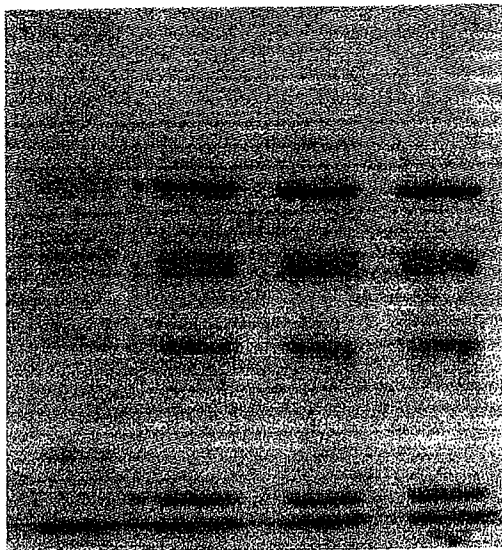
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## Need to be done

- Analyze the importance of the UV lamps for the gel casting;
  - Establish an ideal production line to easily produce an aimed 1M gels per year;
  - Design refinements required to install it in the gel box;
  - Design adaptor for each commercialized machine;
  - Find optimal thermoforming plastic for this specific application;
  - Study the aging of gels and cassettes.
- 

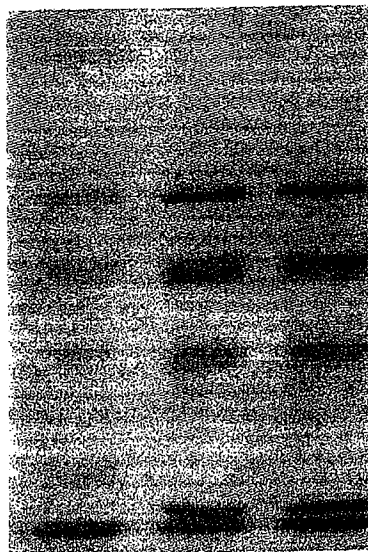
### **TEMED/APS**

**A B B B**



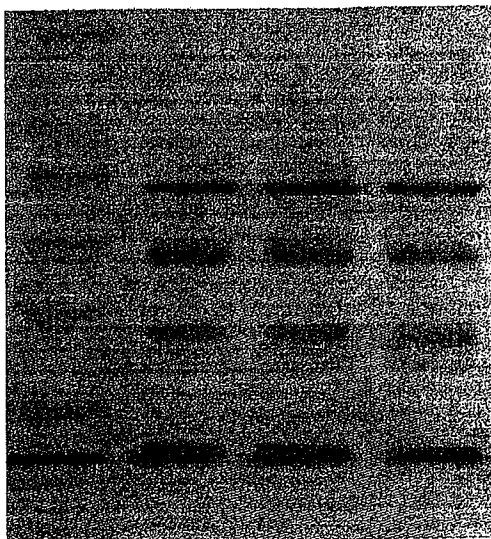
### **Photoinitiator A**

**A B B**



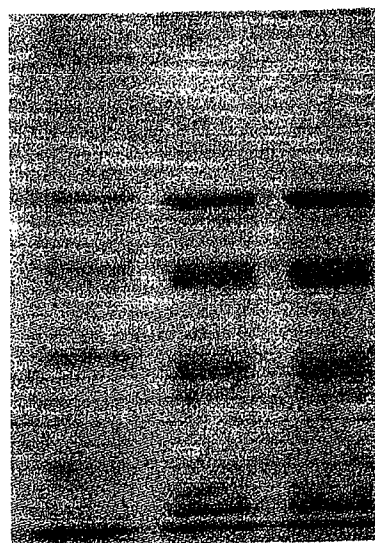
### **Photoinitiator B**

**A B B B**



### **Photoinitiator C**

**A B B**



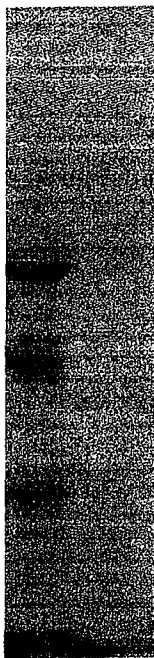
**10% Acrylamide gels**

**Tris-Glycine buffer**

**Glass casting**

**Photoinitiator A**

**B**

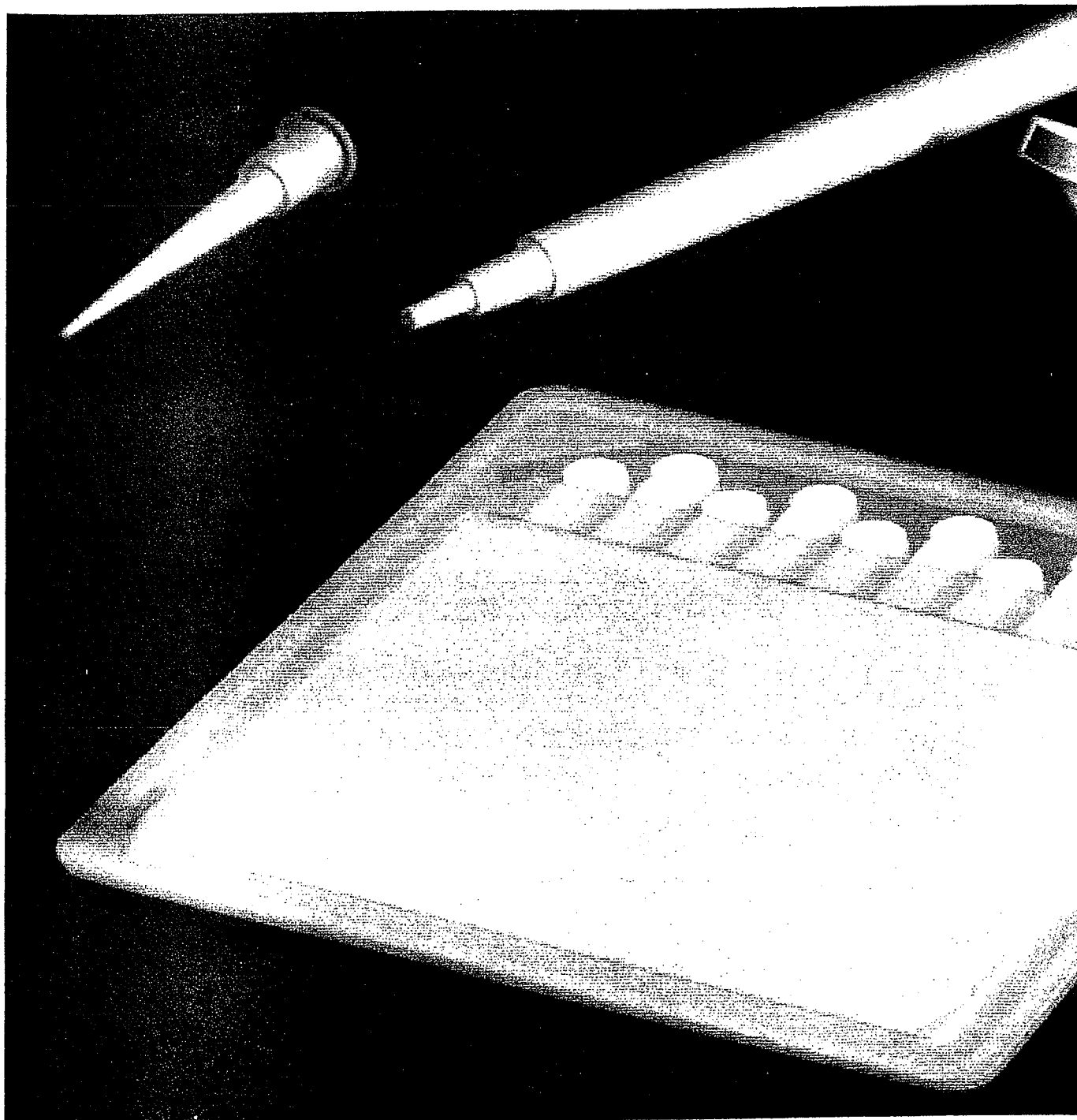


**10% Acrylamide gel**

**Tris-Glycine buffer**

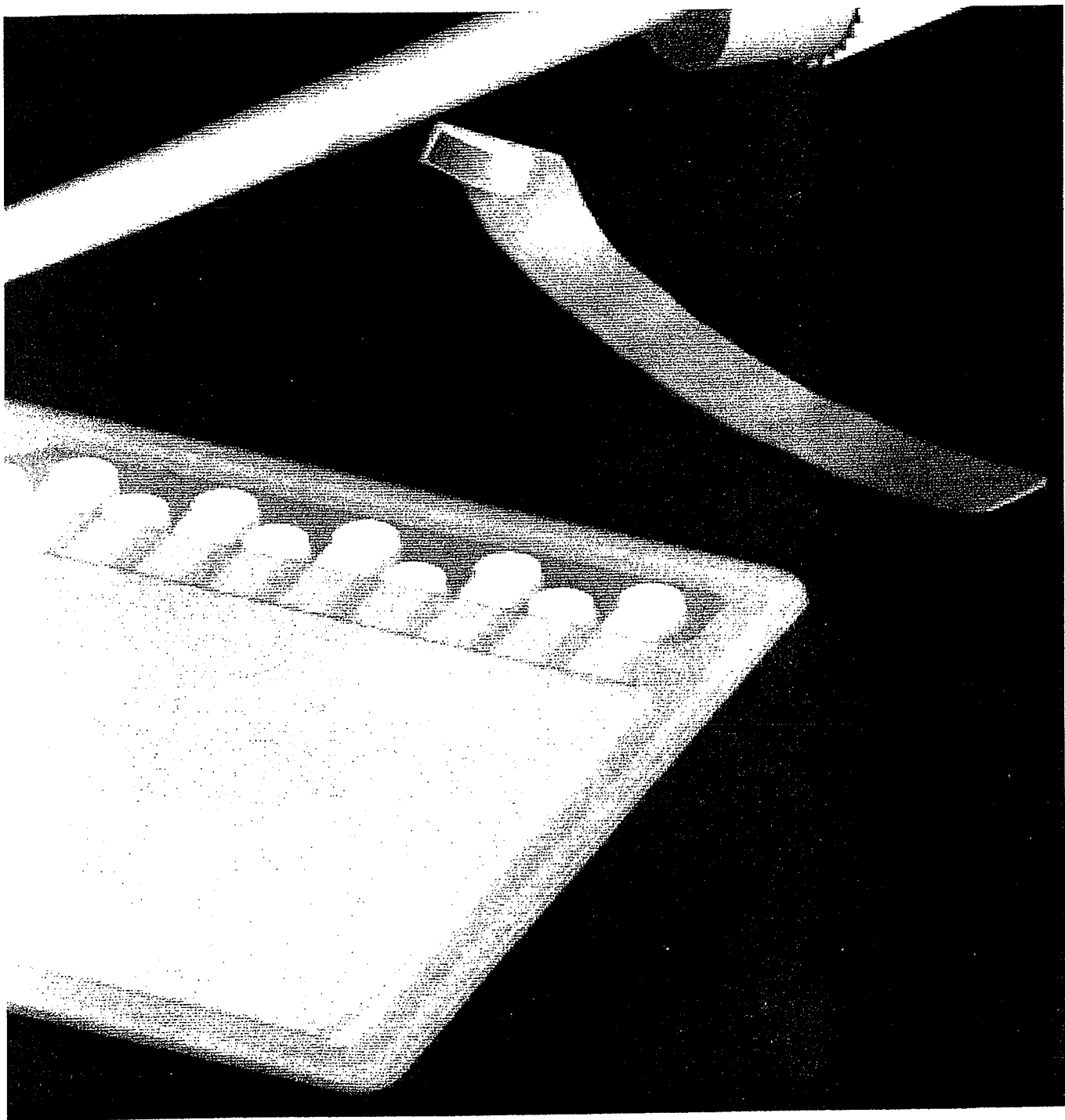
**Plastic casting**



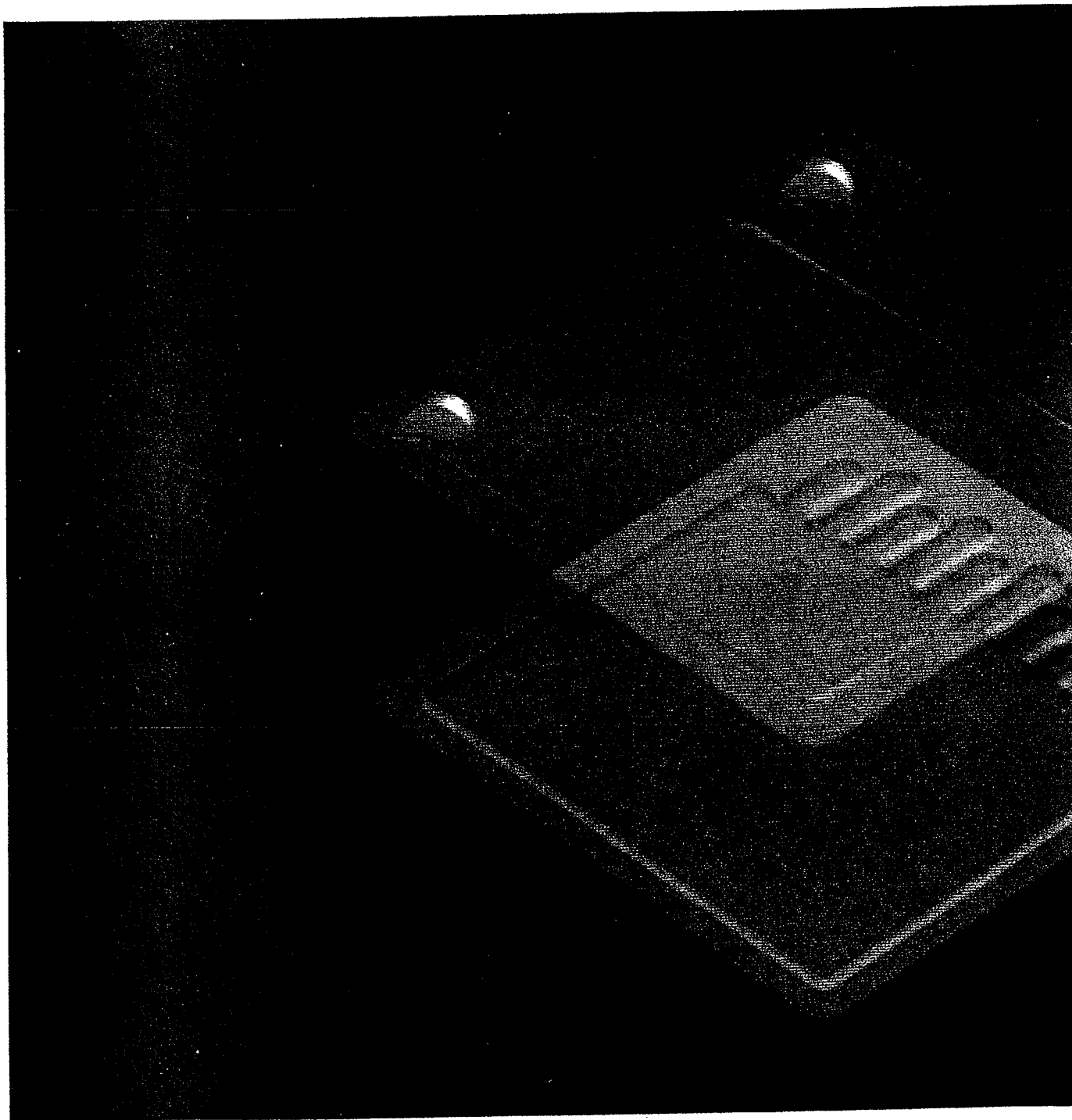


GenID

SoftGel



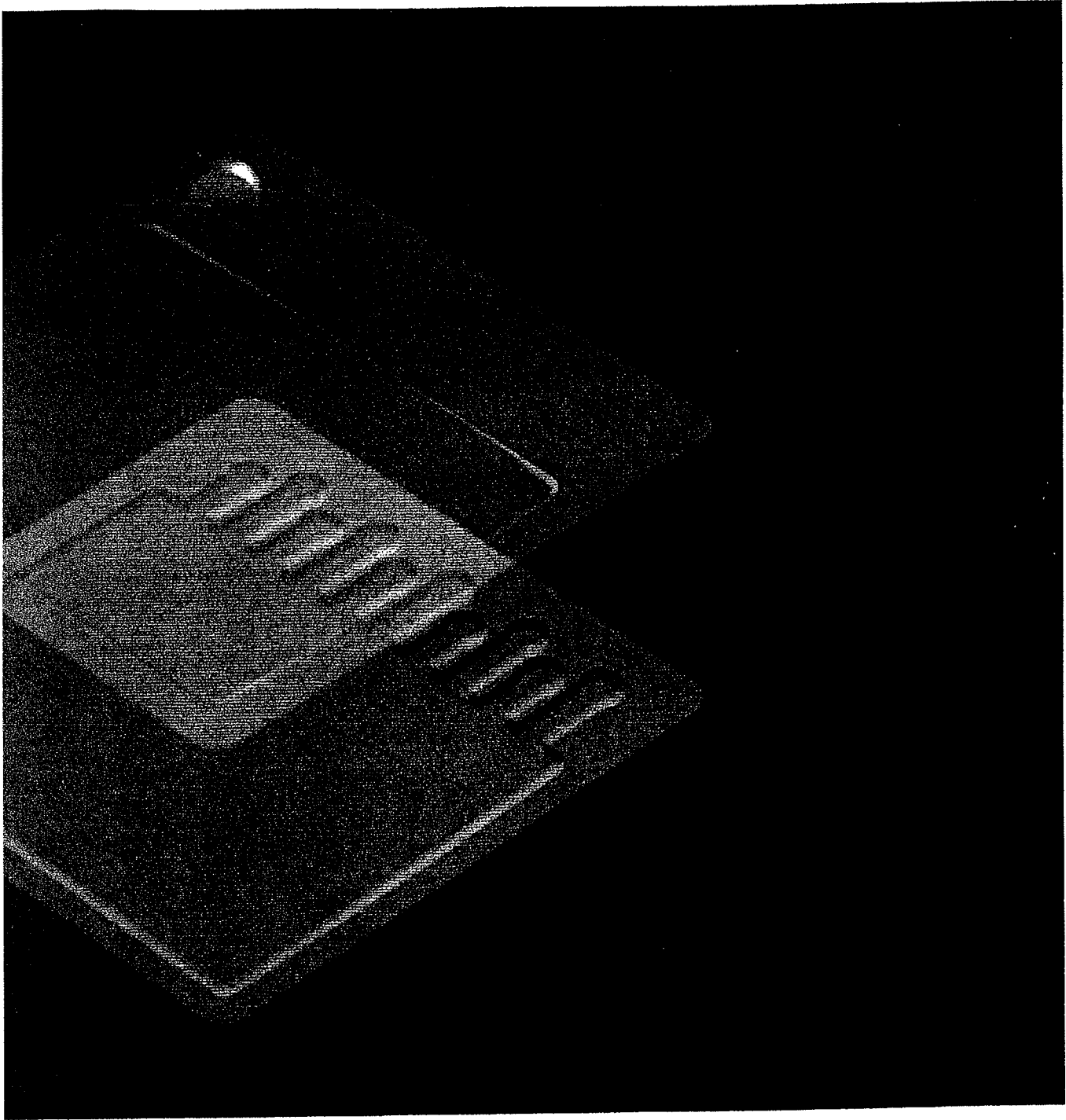
*SoftGel* preliminary concept B



GenID

SoftGel





*SoftGel* preliminary concept B

